EXHIBIT 5

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Infection control hazards of intraoperative forced air warming

Sir,

Perioperative hypothermia is a common problem, particularly during prolonged surgical procedures, and has been associated with a number of complications including, shivering, decreased drug metabolism or clearance, increased bleeding and impaired wound healing.[1] Forced-air warming systems have been shown to be an effective method of preventing hypothermia during a variety of surgical procedures including hip arthroplasty.[2–4] Studies have attempted to demonstrate the benefit of maintaining normothermia throughout surgical procedures in the prevention of postoperative wound infections. However, no studies have addressed the safety of the intraoperative use of forced-air warming blankets during ultraclean orthopaedic procedures, and others have questioned their benefit.[5] A study conducted by the Wound Infection and Temperature Group compared wound infection rates in patients undergoing elective colorectal resection.[6] They demonstrated a significant reduction in wound infection rates in patients actively warmed during surgery using warmed fluids and a forced-air warming system, compared with a control group with no active warming. A more recent study demonstrated the benefit of preoperative forced air warming on reducing wound infection rates after short, clean surgical procedures.[7]

As a result of this limited evidence, the process of using forced-air warming blankets to prevent intraoperative hypothermia is common practice during many surgical procedures. However, there is a wide variation in convection warmers available. Some older models are not fitted with appropriate microbial filters to prevent contamination of the air blown into the blanket.

As part of a general review of theatre practices we investigated a WarmAir warming unit model 133A (Cincinnati sub-zero), routinely used during surgical procedures in an ultraclean orthopaedic theatre. The machine draws air at floor level through a 0.5 μm filter into a non-sealed unit. The air is then blown by a fan through a hose into a disposable porous blanket which is placed over the patient. The blanket is not designed to act as a microbial filter.

Swabs were taken from several locations on both the exterior and interior of the machine and from the distal end of the hose. Heavy growth of bacteria was detected in all samples taken, both from direct plates and enrichment broths. The organisms isolated included coagulasae-negative staphylococci, *Micrococcus* spp., *Bacillus* spp. and *Streptococcus oralis*. Air sampled from the stream blown through the hose of the warmer grew colonies of coagulase-negative staphylococci, *Bacillus* spp., and *Micrococcus* spp. We did not attempt to investigate the value of the blanket as a microbial filter. However, in a situation where contaminated air may come into contact with a prosthetic joint small numbers of organisms normally considered to be non-pathogenic can result in serious complications.

Similar results to these were obtained in a study investigating the potential hazards of several models of convection warmers.[8] They did find that using the recommended blankets attached to the hose prevented the detection of contaminating bacteria on an agar plate placed beneath the blanket. However, because air from the hose is distributed over a relatively larger volume within the blanket, the detection methods used were insensitive.

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At present there seems insufficient evidence to justify the routine use of forced air warming units as an intraoperative measure during ultraclean orthopaedic surgery. Furthermore, there are no available data to indicate whether the airstream from these warming units has any effect on airflow in ultraclean ventilation systems.

Intraoperative use of these machines should be based on thorough risk–benefit assessments. If they are used, they should be sealed units fitted with appropriate microbial filters which are changed according to the manufacturers instructions. The blankets used should be those recommended by the manufacturer, and care should be taken to ensure they are properly sealed to the patient's skin to prevent air contaminating the operative field. Where machines are provided on loan under blanket purchase contracts it is essential that these machines are serviced and upgraded as improved models become available.

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Failure to heal should replace infection rate when monitoring surgical wounds

Sir,

The rate of wound infection following clean surgery has been accepted as a sensitive indicator of asepsis during the peri-operative period. More recently, surgical wound infection rates have been advocated as a measure of the effectiveness of hospital infection control. Is this appropriate?

By the beginning of the 20th century, principles for minimizing microbial contamination of wounds during surgery were well established. Precautions include use of sterile equipment and suture material, disinfection of hands and the surgical site, and theatre ventilation. With strict application of these measures, primary infection of the superficial wound is largely preventable. Even if asepsis is less than perfect and micro-organisms are introduced into the wound, this does not always result in infection as host defence mechanisms help clear contamination and combat infection. Wound exudate, for example, contains neutrophils and plasma proteins such as lysozyme and is actively bactericidal.[1] Factors that contribute to progression from contamination to infection include the presence of foreign material, devitalized tissue, blood clot and other fluid collections. In fact, where standard aseptic measures have been implemented, surgical wound infection may be regarded as a surrogate marker for poor surgical technique rather than ineffective infection control.

Strict asepsis and competent surgical technique do not prevent the infections which follow complicated or prolonged clean surgery, nor those infections which follow 'contaminated' and 'dirty' surgery. Infection rates following these procedures may be significantly reduced by the judicious use of prophylactic antibiotics, appropriately timed in relation to surgery. Many other peri-operative factors influence the incidence of surgical wound infection. These include reduced oxygen tension in tissues[2] and hypothermia.[3] Systemic and local warming reduces infection and also independently enhances the rate of healing. Host factors which are thought to influence wound infection include diabetes mellitus, nutritional status, age, adiposity and smoking. Wound management and the use of appropriate